Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir (Viekira Pak)

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Drug Summary

The all-oral regimen ombitasvir-paritaprevir-ritonavir and dasabuvir, with or without ribavirin, provides another option for patients with chronic HCV genotype 1a infection (without cirrhosis or with compensated cirrhosis when given with ribavirin) and genotype 1b (without cirrhosis or with compensated cirrhosis). Overall, this combination regimen appears to be well tolerated, but severe hepatotoxicity associated with hepatic decompensation and death were reported post-marketing, mainly in patients with moderate-to-severe hepatic impairment (Child-Pugh B and C). The potential risk of severe liver complications in some patients underscores the importance of staging patients prior to treatment to identify any with moderate-to-severe hepatic impairment. This regimen is dosed twice daily and requires a higher pill burden than some other direct-acting antiviral options, particularly when ribavirin is included. Like elbasvir-grazoprevir, this combination has been shown to be safe and effective in patients with advanced kidney disease.

Class and Mechanism

The Viekira Pak is an all-oral regimen comprised of four medications: ombitasvir, paritaprevir, ritonavir, and dasabuvir. This regimen can be used with or without ribavirin. In the Viekira Pak, the ombitasvir-paritaprevir-ritonavir are combined as a fixed-dose tablet and the dasabuvir is a separate tablet. Ombitasvir is a NS5A inhibitor with potent pangenotypic picomolar antiviral activity, paritaprevir is an inhibitor of the NS3/4A serine protease, and dasabuvir is a nonnucleoside NS5B polymerase inhibitor. Ritonavir is a potent inhibitor of CYP3A4 enzymes and is used as a pharmacologic booster for paritaprevir—it significantly increases peak and trough paritaprevir plasma concentrations, as well as the area under the curve of paritaprevir. Ritonavir was originally developed and FDA-approved as an HIV protease inhibitor; it does not have activity against HCV.

Manufacturer for United States
The *Viekira Pak* (vee-KEE-rah-pak) contains the fixed-dose combination of ombitasvir-paritaprevir-ritonavir plus dasabuvir (Figure 1) and (Figure 2). It is manufactured by AbbVie. The drug paritaprevir was discovered and developed as part of a collaborative effort between AbbVie and Enanta Pharmaceuticals. Ribavirin, which is recommended for use with the *Viekira Pak* in specific patient populations, is manufactured by multiple companies in the United States and is available in generic formulations.

### Cost and Medication Access

The wholesale acquisition cost (WAC) for a 12-week treatment course with *Viekira Pak* is $83,319. The cost for a 24-treatment course with the *Viekira Pak* is $166,638. The exact added cost of ribavirin, if used, is more difficult to determine because of variable daily doses when using the recommended weight-based dosing and the availability of ribavirin through multiple companies. Roughly, the cost of a 12-week treatment with generic ribavirin is roughly $700 and for 24 weeks it is $1400.

The AbbVie patient assistance program (proCeed) offers a broad range of patient support and financial information. The program can also be accessed at the proCeed page on the *Viekira Pak* web site or by calling 1-844-2-PROCEED (1-844-277-6233).

### Adverse Effects

On October 22, 2015 the United States FDA issued a Drug Safety Warning that treatment with ombitasvir-paritaprevir-ritonavir and dasabuvir (*Viekira Pak*) can cause serious liver injury, mostly in patients with underlying advanced liver disease. In most of the reported cases, the liver injury occurred within 1 to 4 weeks of starting treatment. Available data from clinical trials have demonstrated excellent tolerance with the ombitasvir-paritaprevir-ritonavir and dasabuvir regimen. The most common (greater than 10%) adverse effects observed in clinical trials when used without ribavirin have been fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia. The concomitant use of ombitasvir-paritaprevir-ritonavir and dasabuvir with ethinyl estradiol-containing medications can result in significant elevations in hepatic aminotransferase levels; accordingly patients should discontinue any ethinyl estradiol-containing medications prior to starting ombitasvir-paritaprevir-ritonavir and dasabuvir. Ribavirin can cause significant adverse effects, including hemolytic anemia. Further, ribavirin is highly teratogenic and embryocidal, and extreme care must be given to avoid pregnancy during therapy and for 6 months after completing therapy; this pertains both to treatment of women receiving ribavirin treatment and women whose male partners are receiving ribavirin therapy. Consult the ribavirin prescribing information for detailed information on ribavirin-related adverse effects and precautions for use of ribavirin.

### Key Drug Interactions

For complete information on ombitasvir-paritaprevir-ritonavir and dasabuvir-related drug interactions, see the Drug Interactions section in the Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir (*Viekira Pak*) Prescribing Information.